

# The impact of indocyanine green (ICG) angiography in multiple diagnostic imaging for the management of exudative age-related macular degeneration (ARMD): a single blind prospective randomised controlled trial of fluorescein angiography vs FA & ICG

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/04/2011	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0295142266

## **Study information**

**Scientific Title**

### **Study objectives**

Attempt to identify ophthalmic features and positive predictive value for ICG as 'diagnosis and management modifier'. The use of indocyanine green angiography (ICG) may facilitate the identification of lesions that have been proposed to respond to laser treatment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Prospective randomised controlled trial and pilot study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Not Specified

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Eye Diseases: Age-related macular degeneration (ARMD)

### **Interventions**

Interventions are fluorescein angiography compared with fluorescein angiography and indocyanine green angiography.

Added 05/09/2008: trial was stopped due to new treatments available.

### **Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Moderate and severe visual loss defined as loss of three lines or 15 letters (doubling of visual angles) and loss of 6 lines or 30 letters respectively, on a log MAR visual acuity chart, at 4,8 and 12 months.

**Secondary outcome measures**

1. ICG rates modification of fluorescein based diagnosis and management
2. Specificity and sensitivity of ophthalmic signs predictive of ICG findings

**Overall study start date**

24/05/2004

**Completion date**

24/05/2006

**Reason abandoned (if study stopped)**

New treatments available

## **Eligibility**

**Key inclusion criteria**

240 patients, of whom 24 are estimated to have retinal angiomatous proliferation (RAP).

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

240

**Key exclusion criteria**

No specific exclusion criteria

**Date of first enrolment**

24/05/2004

**Date of final enrolment**

24/05/2006

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### Paybody Eye Unit

Coventry

United Kingdom

CV1 4FH

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House

79 Whitehall

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dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Government

## Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK), NHS R&D Support Funding

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration